DECLARATION OF DUAFALIA DUDIMAH PhD

I, Duafalia Dudimah, do hereby declare as follows:

1. I am over eighteen years of age and am competent to testify regarding the matters stated in this declaration. I give this declaration voluntarily. I have not been promised any benefit, been coerced, or been threatened in any manner in exchange for the testimony in this declaration.

2. I am employed by Covance Inc. ("Covance"). I was initially hired by Covance in April 2015 as a Clinical Research Assistant. On June 1, 2016, I became a Clinical Research Associate ("CRA") I at Covance.

3. I have a Bachelor of Science in biology and a PhD in immunology. I have significant research experience in the fields of cancer and immunology.

4. Covance is a research company that contracts with pharmaceutical companies to assist in the development of drugs and medical devices. The overall responsibility of a CRA at Covance is to monitor and supervise clinical medical research trials, which test the safety and effectiveness of new drugs and medical treatments. As a CRA I, I have general oversight over the administration of clinical trials. Although I do not actually conduct the trials, I am responsible for administering nearly every aspect of these clinical trials to ensure the accuracy of the clinical trial data and to ensure subject safety. In that sense, I really have general oversight responsibility for the entire trial.

5. Clinical research trials consist of several different phases. Each of the clinical trial phases requires the participation of CRAs. Some CRAs are assigned to particular phases, while others work on all phases of clinical trials. In my case, I have experience in all phases.

6. A CRA can be assigned to a single study or multiple studies depending on the workload and number of sites the CRA is responsible for. The number of CRAs assigned to a clinical trial varies depending upon the complexity and size of a trial. Although multiple CRAs can be assigned to a clinical trial, there is generally only one CRA assigned to each clinical site.

7. Clinical trials are conducted at the laboratories of Covance's clients, and at the offices of participating physicians. A significant portion of my job is spent traveling to and visiting clinical sites. When I am not traveling to and visiting clinical sites, I work from home. I have no office at Covance.

8. The requirements of a trial are set forth in a written protocol that is prepared by the pharmaceutical company that is Covance's client, in accordance with regulations established by the Food and Drug Administration. The protocol sets forth the objectives of the trial, the methods by which the trial is designed to operate, and procedures that must be followed in order to safeguard the health of participants and certain metrics to assess the effectiveness of the clinical trial. If in my judgment a protocol is unclear or vague, I take the initiative to raise the issue with my clinical team lead. My clinical team lead and I then discuss the issue to determine what actions should be taken to clarify the protocol.

9. I interpret the protocols to ensure that the trials are conforming to the requirements of the protocols, and to make adjustments if necessary. In addition to the protocols, I am responsible to making sure that the clinical trials are conducted according to International Council for Harmonization ("ICH") and Good Clinical Practice ("GCP") guidelines.

10. Prior to the time the clinical trial actually begins, I conduct a pre-trial qualification visit to the offices of physicians who are scheduled to participate in the clinical trial. The purpose of the pre-trial qualification visit is for me to analyze and determine whether

the facilities are adequate, and that the physician and staff understand the requirements of the trial.

11. I use objective criteria as well as my personal judgment to assess whether to recommend that a physician be qualified to conduct a trial. My interaction with the principal investigator and staff and whether the principal investigator has a genuine interest in conducting the study are factors that I take into account in assessing the qualifications of a physician. After each pre-trial qualification visit, I prepare a report where I make a recommendation as to whether the physician should qualify to conduct the trial. In my experience, my recommendations are usually followed.

12. After the pre-qualification visit, I am responsible for reaching out to the qualifying site and arranging a site initiation visit. The purpose of this meeting is to train the doctor and doctor's staff regarding the proper procedures required in the clinical trial. I handle this training, which usually involves a power point presentation that describes the process that is involved in the clinical trial.

13. Although I do not participate in screening patients who have been selected to participate in a study, I am the first point of contact if a clinical site has any doubt as to whether a patient meets the inclusion/exclusion criteria for a study. Depending upon the specific facts and circumstances, I either answer their inquiry or use my judgment to refer the inquiry to the correct medical professional.

14. Once the clinical trial begins, I am responsible for performing regular site visits to ensure that the trial is being conducted in the proper manner, and that the trial is free from errors that could taint or discredit its results. It is up to me to use my experience and judgment as well as the protocol guidelines to identify potential problems in clinical trials, based

upon the information uploaded by the site. It is my responsibility to recognize incorrect trends and deviations in data and take the appropriate steps to ensure that the data is corrected.

15. My review of patient data is also to ensure patient safety. For example, in a study where a new drug was being tested, I reviewed patient data and a patient's creatinine levels were higher than the upper limit that a patient's levels should have been when taking the new drug. I recognized that this was a protocol deviation that threatened patient safety and took appropriate steps to remedy the issue with the clinical trial site.

16. Part of my responsibility is to review the forms completed by each participating physician's office (these forms are called "Case Report Forms"). I have to make sure that the Case Report Forms are filled out accurately and completely, that the information contained in the Case Report Forms appear to be accurate, conforms to the GCP guidelines and protocols, and that no gaps exist in the information recorded at each site. Participating sites are required to enter all data into an electronic data capture system; therefore, I have access to all of the information in connection with a clinical trial, and I can monitor this data remotely as necessary to identify any breaches of the protocols. I estimate that I spend approximately 10-20% of my time preparing reports.

17. I do not perform routine data entry or any significant clerical tasks as part of my job as a CRA I. I do utilize the Company's Clinical Trial Management Software ("CTMS") system to prepare written reports that summarize the status of the clinical trials that I am assigned to including trip reports which are prepared after every site visit. On every trip report that I have prepared, I have had to determine whether I believe the clinical site is still qualified to participate in the study.

18. The frequency in which I visit a site varies significantly depending on the number of patients enrolled at a site or ongoing issues at the site. For example, when a clinical trial site is going to close and the site is having issues with the accuracy of data, I tend to visit the clinical site more often to ensure that all queries are resolved accurately and in a timely manner. The frequency of my visits is also dependent upon the clinical trial's specific protocol.

19. Along with the frequency of visits, the time I actually spend traveling to and from clinical trial sites varies depending upon the clinical trial sites that I am assigned to.

20. The vast majority of my work hours are spent either engaged in visits to various clinical trial sites; preparing for those visits (by reviewing the protocols for the particular clinical trials I am working on); or traveling to and from those sites. My travel schedule varies from week to week depending upon the clinical trial sites to which I am assigned.

21. I take meal breaks and other types of breaks whenever I choose. No one dictates my break schedule and I am free to run personal errands or go to other appointments during the day in my discretion. I have an incredible amount of flexibility in my schedule and any regimented or inflexible schedule would prohibit me from performing my job duties, especially given the travel that is required.

22. Because I work out of my home, I do not have daily contact with the supervisor I report to. I communicate with my supervisor as necessary and occasionally by phone, usually no more than once a month. My supervisor does not set my schedule or dictate when I take breaks.

23. I declare under penalty of perjury that the foregoing statement is true and correct.

Executed on this 03 day of November, 2017 in Nashville.

DUAFALIA (FRED) DUDIMAH